

December 20, 2001

Walter L. Jones
Pine Chemicals Association
P.O. Box 105113
Atlanta, GA 30348-5113

Dear Mr. Jones:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Tall Oil and Related Substances, posted on the ChemRTK Web Site on July 17, 2001. I commend The Pine Chemicals Association (PCA) for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program website EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

The proposed category of seven mixtures appears to be adequate for health effects and ecotoxicity endpoints. The Association has chosen distilled tall oil as the representative substance for health and environmental effects testing. However, tall oil pitch, its sodium salt, and disproportionated tall oil appear to differ significantly from the others; you need to consider whether some testing of these substances is necessary to characterize them adequately or confirm that data on distilled tall oil can apply to them.

The Test Plan indicates that there is no need to measure photodegradation and transport and distribution for these chemicals. Although this is a reasonable approach for the mixtures, estimated photodegradation and transport and distribution data for the major constituents of tall oil, disproportionated tall oil, and tall oil acidulation wastewater would be useful in evaluating the category's fate properties (See Test Plan comments).

EPA agrees with the proposed mammalian and *in vitro* testing using distilled tall oil as a representative substance. However, the PCA needs to explain how the toxicity of distilled tall oil will be similar and applicable to the three substances that may be significantly different. Some acute toxicity and possibly other testing on tall oil pitch and disproportionated tall oil may be necessary to support this position.

EPA agrees with the PCA proposal of acute toxicity tests in fish, daphnia, and algae because of our concerns for the toxic potential of resin acids. EPA also recommends 21-day chronic toxicity testing for daphnia, given the dispersibility in water and high log Kow of other tall oil constituents. All aquatic testing should follow the appropriate OECD guidelines.

As with other submissions where the available data are either inadequate or insufficiently documented, this case will remain open until adequate documentation is in hand.

EPA will post this letter and the attached Comments on the Chemical RTK web site within the next few days. As noted in the comments, we ask that the PCA advise the Agency, within 60 days of the posting on the Chemical RTK website, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comment button or through the TSCA Assistance Information

Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsc hotline@.epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: Tall Oils and Related Substances

SUMMARY OF EPA COMMENTS

The sponsor, Pine Chemicals Association, submitted a test plan and robust summaries to EPA for Tall Oil and Related Substances dated May 23, 2001. EPA posted the submission on the ChemRTK website on 17 July 2001. The proposed information-gathering plan is for seven mixtures (see Category Definition, below) considered by the sponsor to constitute a category.

EPA has reviewed this submission and reached the following conclusions:

1. Category Justification. The proposed category of seven mixtures appears to be adequate for health effects and ecotoxicity endpoints.
2. Representative substance. The submitter has chosen distilled tall oil as the representative substance for health and environmental effects testing. Of the category members, tall oil pitch, its sodium salt, and disproportionated tall oil appear to differ significantly from the others; the submitter needs to consider whether some testing is necessary to characterize them adequately or confirm that data on distilled tall oil can apply to them.
3. Physicochemical Data. The submitter's approach is acceptable.
4. Environmental Fate Data. The Test Plan indicates that there is no need to measure photodegradation and transport and distribution for these chemicals. Although this is a reasonable approach for the mixtures, estimated photodegradation and transport and distribution data for the major constituents of tall oil, disproportionated tall oil, and tall oil acidulation wastewater would be useful in evaluating the category's fate properties (See Test Plan comments below).
5. Health Effects. EPA agrees with the submitter's proposed testing for repeated dose toxicity with reproductive and developmental toxicity screens and for genotoxicity in bacteria and mammalian cells using distilled tall oil as a representative substance. However, the submitter needs to explain how the toxicity of distilled tall oil will be similar and applicable to the three substances that may have significantly different compositions. It may be necessary to conduct acute toxicity and possibly other testing on tall oil pitch and disproportionated tall oil to support this position.
6. Ecological effects. EPA agrees with the submitter's proposal of acute toxicity tests in fish, daphnia, and algae because of the presence of resin acids in all category members (see comments below under Test Plan). EPA also recommends 21-day chronic toxicity testing for daphnid, given the low water solubility and high log Kow of tall oil compounds. All aquatic testing should follow the OECD guidelines for hydrophobic substances and poorly water-soluble chemicals.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON TALL OILS AND RELATED SUBSTANCES CATEGORY CHALLENGE SUBMISSION

Category Definition

Tall Oil and Related Substances is a category of seven substances:

<u>Name</u>	<u>CAS No.</u>
Tall oil; Distilled tall oil	8002-26-4
Tall oil, sodium salt	65997-01-5
Tall oil, potassium salt	68647-71-2
Disproportionated tall oil	68152-92-1
Tall oil pitch	8016-81-7
Tall oil pitch, sodium salt	68140-16-9
Tall oil soap acidulation wastewater	65997-02-6

Crude tall oil, a complex mixture of fatty acids and resin acids derived from wastes obtained from the pulping of trees, is processed by fractional distillation to yield distilled tall oil and other products.

A typical distilled tall oil derived from trees from the southeastern United States is composed of 68% C₁₆ to C₁₈ fatty acids (with C₁₈ fatty acids as the major component of this fraction) and 29% resin acids (abietic acid and other resin acids and derivatives). These percentages vary with the source tree, processing conditions, etc.

Catalytic treatment of tall oil to remove conjugated double bonds provides disproportionated tall oil. Tall oil pitch is a tarry mixture of high boiling, high molecular weight compounds that remains after other fractions have been distilled from tall oil. The salts in the category are aqueous dispersions from neutralization of the corresponding fractions. Tall oil soap acidulation wastewater consists of 1-2% tall oils in a 12% sodium sulfate solution.

One component of tall oil not discussed in the test plan is the 5% unsaponifiable matter. It is assumed that this unsaponifiable matter is composed of "terpenes and sterols," although this point is not clearly delineated in the test plan. However, overall the category definition is adequately clear, descriptive and limited.

Category Justification

The category rationale is based on the similarities in the composition of the substances, which are predominantly composed of fatty acids, followed by resin acids and a small amount of unsaponifiable matter. Another reason cited by the Submitter for grouping these substances is that they are all derived from crude tall oil. Inclusion of salts of category members is reasonable. The overall category approach is in general reasonable.

Test Plan

The submitter has proposed one representative member of the category for the aquatic, mammalian, and genetic toxicity testing. All other substances in the category, except where noted below, will be tested individually for physicochemical properties (partition coefficient and water solubility) and biodegradation.

Representative Test Substance

The submitter has chosen tall oil as the representative test substance for the category. For mammalian toxicity testing, the selection was made because (1) the chemical composition of distilled tall oil is similar to all of the other substances in the category, including crude tall oil; (2) the distilled form is “more uniform in composition and physical state” than crude tall oil; and (3) crude tall oil is typically used as distillation feedstock. However, it is unclear whether the distilled tall oil will adequately represent disproportionated tall oil and tall oil pitch in toxicity testing. EPA believes that the process of catalytic conversion of conjugated double bonds during the production of disproportionated tall oil could significantly change the chemical composition of the fatty acids in this substance relative to the original distilled tall oil. The test plan includes no data on the typical chemical composition of disproportionated tall oil, nor is there any discussion about how this change in the chemical composition of fatty acids or resin acids will affect the toxicity of this substance.

Similarly, tall oil pitch and its sodium salt are also expected to have significantly different compositions relative to the original distilled tall oil stock. The submitter, however, has not provided a typical chemical analysis of tall oil pitch because developing an adequate analytical technique has not been possible. This inability to fully characterize the tall oil pitch suggests that substantive changes may have occurred in the processing. EPA believes that the toxicity of this material could be different from that for the distilled tall oil. Although environmental exposure potential will be limited for tall oil pitch, its sodium salt has a greater exposure potential because of its use in the asphalt industry. The sponsor needs to provide a discussion on toxicity of these substances and/or consider testing them for acute toxicity and other effects.

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient)

The sponsor’s approach for melting point, boiling point, vapor pressure, partition coefficient, and water solubility is acceptable for the purposes of the U.S. HPV Challenge Program.

Environmental Fate (melting point, boiling point, vapor pressure, water solubility, and partition coefficient)

The sponsor’s approach for stability in water (hydrolysis) and biodegradation is acceptable for the purposes of the U.S. HPV Challenge Program.

Photodegradation – The submitter states on page 16 of the test plan: “Due to their low water solubility and lack of any vapor pressure at ambient temperatures, there is no opportunity for any of these chemicals to enter the atmosphere. Thus, photodegradation is irrelevant. In addition, based on the constituents of these complex mixtures, there is no reason to suspect that they would be subject to breakdown by a photodegradative mechanism. Consequently, this endpoint will not be determined for any of the substances in this category.”

EPA finds the submitter’s conclusion inconsistent with values from estimation programs for tall oil, disproportionated tall oil, and tall oil acidulation wastewater. Since many of the individual mixture components have low water solubilities and moderate Henry’s Law constants, volatilization from water may be significant. Estimated values indicate that if these substances enter the atmosphere in this fashion, they will be degraded rapidly by reaction with photochemically generated hydroxyl radicals and by reaction with ozone and nitrate radicals (for substances that contain carbon-carbon double bonds). EPA recommends that photodegradation be estimated for tall oil, disproportionated tall oil, and tall-oil acidulation wastewater, or for their major constituents.

Chemical Transport and Distribution in the Environment – The submitter states on page 16 of the Test Plan that a fugacity (Level III) model requires parameters (such as molecular weight, partition coefficient,

boiling point, melting point, half-life values for air, water, soil, sediment) that are specific to individual components. Although parameter values for the individual components are not truly representative of the

mixtures in this category, EPA believes that fugacity calculations for the major components of each mixture would prove useful in understanding the environmental behavior of the mixtures.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Information is available in the robust summaries only for acute oral toxicity of crude tall oil. The submitter considered the data for this endpoint to be adequate, and no additional acute toxicity testing is planned. Data are not available for repeated dose, reproductive, developmental, or genetic toxicity endpoints. The submitter proposes to conduct on the representative test substance a combined repeated-dose toxicity test with reproductive and developmental toxicity screens (OECD Guideline 422) and genotoxicity tests for gene mutation in bacteria (OECD Guidelines 471) and *in vitro* chromosomal aberrations in mammalian cells. The proposed testing could satisfy the requirements for toxicity testing provided that the submitter can demonstrate that the toxicity of disproportionated tall oil and tall oil pitch will be similar to that of the representative test substance (distilled tall oil), or conduct acute toxicity testing, at a minimum, to support the analogy.

Ecotoxicity (fish, invertebrate and algal toxicity)

EPA agrees with the proposed acute toxicity testing of fish, daphnia, and algae for tall oil because of the presence of resin acids for which EPA has standing acute toxicity concerns. In addition, EPA recommends the daphnid reproduction 21-day chronic test using a flow-through method with measured concentrations. High log Kow chemicals having an anionic group, such as long-chain fatty acids, are dispersible in water and can achieve optimal aquatic effects in short-term and long-term tests. EPA further recommends that the water solubility test be performed at pH7 prior to the aquatic toxicity testing. The tall oil should then be tested for environmental toxicity up to the dispersible limit as the sodium salt, at pH 7, at 25°C, and a dilution water hardness of less than 180 mg/L as CaCO₃. No dispersants should be used owing to possible interference with inherent toxicity of test chemicals. Also, EPA agrees with the submitter's proposal to test chemicals under conditions that maximize solubility but reduce exposure to insoluble fractions that may cause nonspecific toxicological effects. EPA cautions that these conditions should incorporate approved analytical methods and should follow the Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (OECD, June 2000—available on the OECD website at <http://www.oecd.org/ehs/test/monos.htm>).

Specific Comments on the Robust Summaries

No comments.

Followup Activity

EPA requests that the Submitter advise the Agency within 60 days of any modifications to its submission.